The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

Paper No. 35

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ALAN R. HIRSCH

Application No. 09/211,507

ON BRIEF

MAILED

AUG 2 6 2004

U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

Before WINTERS, ADAMS, and GRIMES, <u>Administrative Patent Judges</u>.
GRIMES, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 2, 4-6, 9-11, 35, and 39-44, all of the claims remaining. Claim 1 is representative and reads as follows:

1. A method for altering blood flow to the vagina of a female individual, comprising:

administering to the female by inhalation of an odorant effective to alter blood flow to the vagina;

wherein the odorant is selected from the group consisting of a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a mixture of lavender and pumpkin pie odorants, a mixture of baby powder and chocolate odorants, and combinations thereof.

The examiner relies on the following reference:

Doty, "The Smell Identification TestTM Administration Manual," <u>Sensonics, Inc.</u>, pp. 1-22 (1983)

Claims 1, 2, 4-6, 9-11, 35, and 39-44 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled.

Claims 1, 2, 4-6, 9-11, 35, and 39-44 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

We reverse both rejections.

Procedural Background

According to USPTO records, the instant application is the parent of application 09/707,655, filed Nov. 7, 2000. The '655 application was the subject of an earlier appeal to this board (Appeal No. 2003-1468, decided March 26, 2004). The claims involved in that appeal were directed to an article of manufacture, intended for use in the method claimed in this application, which had been rejected for nonenablement and indefiniteness on the same grounds as the instant claims. In Appeal No. 2003-1468, we reversed those rejections for essentially the same reasons that follow.

Technical Background

The instant application discloses a "non-invasive[,] . . . convenient, safe, and easy to perform" method for "enhancing female sexual capacity and response." Specification, page 3. The disclosed method involves an "odorant [that] can be administered in an amount sufficient to increase vaginal blood flow of the female individual." Page 4. "Examples of odorants and odorant mixture[s] that can be administered . . . [include] a mixture of licorice-based odorant and banana nut bread

odorant, a mixture of a licorice-based odorant and cucumber odorant, . . . a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants." <u>Id.</u>

The specification discloses that "[s]uch odorants are commercially available, for example, from International Flavors and Fragrances, Inc. (IFF, New York, NY), Energy Essentials, AromaTech, Inc. (Somerville, NJ), Florasynth, Inc (Teterboro, NJ), and as essential oils." Id.

Discussion

Claim 1 is directed to a "method for altering blood flow to the vagina of a female individual, comprising administering to the individual by inhalation" any of the following mixtures of odorants: licorice-based and banana nut bread, licorice-based and cucumber, lavender and pumpkin pie, or baby powder and chocolate.

The examiner rejected all of the claims as indefinite and nonenabled.

1. Definiteness

We will start with definiteness. <u>See In re Moore</u>, 439 F.2d 1232, 1235, 169
USPQ 236, 238 (CCPA 1971) (Analysis of a claim under § 112 "should begin with the determination of whether the claims satisfy the requirements of the second paragraph. .

. [T]he claims must be analyzed first in order to determine exactly what subject matter they encompass.").

The examiner rejected the claims as indefinite, on the basis that the smells recited in the claims are not adequately defined. The examiner asserted, for example, that the smell of pumpkin pie or banana nut bread can differ depending on the ingredients in a particular recipe; that baby powders from different manufacturers can

have different smells; that the smell of cucumbers can vary depending on, among other things, their ripeness; and that different licorice-based odorants and chocolates can have different smells. See the Examiner's Answer, page 6. He concluded that "[t]he subjective nature of the mixtures of recited odorants . . . causes these claims to be very ambiguous and unclear." Id.

Appellant argues that those of ordinary skill in the odorant arts "would be able to readily ascertain whether a substance had a chocolate aroma, a licorice aroma, a banana nut bread aroma, a cucumber aroma, a lavender aroma, or a baby powder aroma — regardless of whether the substance was the commercial source disclosed, or another synthetic or natural source." Appeal Brief, page 6.

"The standard of indefiniteness is somewhat high; a claim is not indefinite merely because its scope is not ascertainable from the face of the claims." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1342, 65 USPQ2d 1385, 1406 (Fed. Cir. 2003). Rather, a "claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention." Id.

In this case, we agree with Appellant that those skilled in the art would understand the scope of the claims. The record supports Appellant's position that calling particular smells, e.g., "chocolate" or "licorice" is standard practice in the odorant arts. See, e.g., the present specification at page 12, which lists various commercially available odorants that have the specific smells recited in the claims. See also Doty, which is an administration manual for a "smell identification test". Among the smells that test subjects were asked to identify were "chocolate", "licorice", and "pumpkin pie".

See page 5. Thus, Doty provides evidence that the smells recited in the claims are recognizable; i.e., that "chocolate", for example, defines a particular type of smell.

The examiner's reasoning does not contradict this evidence. The examiner argues that, for example, "chocolate" is indefinite because "milk chocolate has a distinct odor from dark chocolate." Examiner's Answer, page 6. This reasoning does not show that the claims are indefinite. Even though milk chocolate may smell different from dark chocolate, both smells would seem to be recognizable as types of "chocolate" smells; the examiner has not shown that those skilled in the art would not recognize both milk chocolate and dark chocolate as having a "chocolate" odor.

Likewise, the examiner may be correct that the smell of cucumbers will vary "based on brand, species, age/ripeness, geographic location in which it is grown, etc." Examiner's Answer, page 5. However, the examiner has presented no basis for concluding that these variables would render the smell of a cucumber unrecognizable; even though cucumbers may vary, all of them would be expected to smell recognizably like cucumbers.

The same goes for the rest of the smells recited in the claims: the examiner has not shown that the terms used in the claims are so ill-defined that those skilled in the art would be unable to tell whether a given smell is or is not within the scope of the claim limitations. Therefore, the examiner has not shown that the scope of the claims could not reasonably be ascertained by those skilled in the art.

Claims are in compliance with 35 U.S.C. § 112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits." Hybritech, Inc. v. Monoclonal Antibodies, Inc.,

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802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1987). That standard is met here. The rejection for indefiniteness is reversed.

2. Enablement

The examiner also rejected the claims as being non-enabled. The examiner's reasoning with regard to enablement is similar to his reasoning with regard to indefiniteness. Specifically, the examiner argues that "[t]he instantly claimed odorants are highly subjective with respect to the actual odors being encompassed and, thus, are not enabled." Examiner's Answer, page 5. That is, because the particulars of the smells recited in the claims can vary, and because it is unpredictable what effect changing the smell would have on the treated subject, "it would take undue experimentation without a reasonable expectation of success for one of skill in the art to prepare and use an article of manufacture having the unusual disclosed/claimed functional effect." Id.

Appellant argues that practicing the claims would not require undue experimentation because "[t]he characteristics of the odorants in the mixtures recited in the claims are well understood in the odorant arts, and one skilled in the odorant arts would readily ascertain and provide suitable odorant mixtures from various sources that have the recited odorant character (e.g., mixture of licorice-based and cucumber odorants, etc.) and that would achieve the desired effect." Appeal Brief, page 11.

We agree with Appellant. The examiner bears the initial burden of showing nonenablement. In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). ("When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it

believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification."). Carrying that burden requires evidence or sound scientific reasoning showing that practicing the full scope of the claims would have required undue experimentation. See In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) ("[E]nablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation.' . . . That some experimentation may be required is not fatal; the issue

In this case, the examiner's case of nonenablement rests on his assertion that the smells of different cucumbers, chocolates, etc. vary, and that this variability is likely to change the effect of the smells on the female subjects being treated. The examiner, however, has provided no evidence to show that any variability in the smells of different samples of cucumber, chocolate, etc. would change the effect of such smells from the effect described in the specification.

is whether the amount of experimentation required is 'undue.'").

For example, the specification asserts that a combination of lavender and pumpkin pie odorants is suitable for practicing the presently claimed invention. That assertion is entitled to a presumption of enablement throughout its scope. See In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) ("[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for

enabling support."). Therefore, the examiner bears the burden of showing that practicing the claimed invention using different lavender and pumpkin pie odorants would have required undue experimentation.

The examiner has not carried this burden. We can accept the examiner's position that there is some variation in the range of smells that would be characterized as "lavender" or "pumpkin pie". The examiner has provided no evidence or sound scientific reasoning, however, to support his position that such variability is a source of unpredictability in the effect of different smells that are recognizable as "lavender" or "pumpkin pie". In support of the assertion of unpredictability, the examiner cites only Doty, which he characterizes as disclosing that "there are numerous variables such as an individual's occupation, general health, psychological state, and age which play a role in assessing sensory function of smell." Examiner's Answer, page 5.

This evidence is inadequate to support the examiner's case. The examiner has provided no reasoning and cited no evidence to show that women's occupation, health, age, or psychological state is likely to affect their physiological reactions to different lavender or pumpkin pie smells. The examiner's position therefore lacks adequate evidentiary or scientific basis. The rejection for nonenablement is reversed.

Summary

The rejections for indefiniteness and nonenablement are reversed.

REVERSED

Sherman D. Winters

Administrative Patent Judge

Donald E. Adams

Administrative Patent Judge

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) INTERFERENCES

Eric Grimes

Administrative Patent Judge

EG/jlb

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